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Supreme Court, U.S.
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No. 94-1531

In The

Supreme Court of the United States

October Term, 1995

NOVOPHARM, INC., and NOVOPHARM LTD.,

Petitioners,

v.

BURROUGHS WELLCOME CO.,

Respondent.

Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

REPLY TO BRIEF OF THE UNITED STATES AS AMICUS CURIAE

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The Amicus Brief argues that "the question of whether Novopharm's offer of proof was sufficient to create a jury question under the Federal Circuit's legal standard is a factbound matter that does not warrant further review." (Amicus Br. 20). Amicus' contention is wide of the mark, for it ignores not only the guidelines established by this Court in *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 106 S.Ct. 2105 (1986), but also the fact that the very premise of the district court's Rule 50(a) judgment has been undermined by the Federal Circuit's decision in this case. The Federal Circuit also ignored key facts in Novopharm's offer of proof which must fairly be considered under the "controlling law."

There is no dispute that the Federal Circuit has now established new controlling law of conception for this case (Amicus Br. 14). The precedent established by the Federal Circuit departs markedly from the definition of conception on which the district court based its Rule 50(a) judgment.

The essential differences explained in the Federal Circuit's decision are:

(1) conception is more than a mere idea (16a);

(2) a person whose contribution to a collaborative effort is experimental may still be a joint inventor if his qualitative contribution contributes to the joint arrival at a definite and permanent idea of the invention as it will be used in practice (15a); and

(3) conception is not complete where subsequent experimentation "especially failures, reveals uncertainty that so undermines the specificity of the inventor's idea that it is not yet a definite and permanent reflection of the complete invention as it will be used in practice" (14a).

Here, the district court could not possibly have decided the case under the "controlling law" as required by Rule 50 because the Federal Circuit changed the controlling law at least insofar as the controlling law was expressed by the district court. The entire basis for the district court's Rule 50(a) judgment was thus fatally undermined.

The Federal Circuit then erred in failing to vacate the district court's judgment and remand the case for trial based on its clarification of the law. Instead, the Federal Circuit not only proceeded to decide the case on the merits, it exacerbated its error by ignoring critical facts in Novopharm's offer of proof, weighing evidence and ascribing credibility to witnesses, thereby improperly usurping the role of the jury. The Federal Circuit thus clearly failed to follow the guidelines of *Anderson* which mandates consideration of all evidence in the light most favorable to Novopharm and leaves credibility determinations, the weighing of evidence and the drawing of legitimate inferences to the jury.

The experimental uncertainty of whether AZT or any other drug could be effective against HIV, the negative experimental results from Duke and the FDA, the essential and unique experimental evaluation and contribution of Dr. Broder and Dr. Mitsuya, scientists who were

"uniquely qualified" to help the Burroughs Wellcome scientists, provide ample factual evidence upon which a jury could conclude that the BW scientists did not have a conception – a definite and permanent idea of the invention – of the use of an effective amount of AZT to treat HIV prior to the key contributions of Drs. Broder and Mitsuya under the controlling law enunciated by the Federal Circuit. Thus, Novopharm is asking this Court not to review facts in order to decide the inventorship question on the merits as Amicus contends, but to review the facts sufficiently to recognize the Federal Circuit's reversible error and to reverse and remand the case to the Federal Circuit.

The Amicus Brief dismisses Novopharm's "pair of hands" argument as a *non sequitur* because the skill employed by the NIH scientists after the adjudged conception date is irrelevant. Amicus' analysis is incongruous in that its reasoning overlooks the very definition of complete conception Amicus itself advocates, and Amicus fails to apply that definition to the Federal Circuit's holding.

Under the Federal Circuit's own precedent, as well as the controlling law announced in this case, as Amicus argues (Amicus Br. 11), a conception is complete only when one of ordinary skill in the art can reduce the invention to practice. Here, the conception of the invention simply could not have been complete on February 6, 1995 as Amicus contends, for the contributions of Drs. Broder and Mitsuya to the invention have been acknowledged to transcend the contribution of a skilled artisan.

Here, as the Federal Circuit found, Dr. Broder and Dr. Mitsuya were not a "mere pair of hands," i.e., they were not merely exercising ordinary skill. Dr. Broder and Dr. Mitsuya exercised "considerable skill" in conducting crucial experiments with their patented cell line (18a). Dr. Broder and Dr. Mitsuya worked independently (18a) of the Burroughs Wellcome scientists in performing their work and making the critical discovery of the effectiveness of AZT amongst other putative drugs that were also tried. Dr. Broder and Dr. Mitsuya were called on to interpret the results they obtained in their admittedly unique experimental system (18a). Dr. Broder and Dr. Mitsuya were "uniquely qualified" not only to perform essential experiments which demonstrated for the very first time the effectiveness of AZT against HIV in a human cell line, but to evaluate and to interpret those experimental results (18a). Dr. Broder and Dr. Mitsuya made critical experimental contributions which completed the conception of the claimed invention – the use of an effective amount of AZT for the therapeutic treatment of HIV.

It is simply not possible to be more than a mere pair of hands, as Dr. Broder and Dr. Mitsuya were in the conception of the use of an effective amount of AZT for the treatment of HIV, and not be a joint inventor. *Sewall v. Walters*, 21 F.3d 411, 415 (Fed. Cir. 1994); *Land v. Dreyer*, 55 F.2d 383, 387 (C.C.P.A. 1946). Indeed, neither the Amicus nor Burroughs Wellcome can point to a *single case* other than this one, where a party found to be more than a "pair of hands" has not been accorded inventorship status.

Novopharm respectfully requests that the Court issue a writ of certiorari to review the judgment of the Court of Appeals for the Federal Circuit.

Respectfully submitted,

Date December 26, 1995

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